

§Appl. No. 10/078,531  
Amdt. dated April 14, 2006  
Reply to Office Action of, October 14, 2005

**Listing of Claims:**

Please **amend** the claims as follows:

**Claim 1 (Cancelled)**  
**Claim 2 (Cancelled)**  
**Claim 3 (Cancelled)**  
**Claim 4 (Cancelled)**  
**Claim 5 (Cancelled)**  
**Claim 6 (Cancelled)**  
**Claim 7 (Cancelled)**  
**Claim 8 (Cancelled)**  
**Claim 9 (Cancelled)**  
**Claim 10 (Cancelled)**  
**Claim 11 (Cancelled)**  
**Claim 12 (Cancelled)**  
**Claim 13 (Cancelled)**  
**Claim 14 (Cancelled)**  
**Claim 15 (Cancelled)**  
**Claim 16 (Cancelled)**

**Claim 17 (Currently Amended)** An isolated polypeptide comprising a polypeptide which is:

- (a) a polypeptide having at least 70% amino acid sequence identity to ~~a second polypeptide having an the~~ amino acid sequence ~~comprising~~ set forth in SEQ ID NO: 2, or fragments comprising at least ten contiguous amino acids thereof;
- (b) a polypeptide having at least 95% amino acid sequence identity to ~~a second polypeptide having an the~~ amino acid sequence ~~comprising~~ set forth in SEQ ID NO: 2, or fragments comprising at least ten contiguous amino acids thereof;
- ~~(c) a polypeptide comprising a sequence chosen from SEQ ID NO: 2, or fragments comprising at least ten contiguous amino acids thereof;~~
- ~~(d)~~(c) a polypeptide capable of generating antibodies having binding specificity for a polypeptide having a sequence chosen from SEQ ID NO: 2 which comprises ~~, or fragments comprising~~ at least ten contiguous amino acids thereof;
- ~~(e)~~(d) an epitope bearing portion of a polypeptide having a sequence chosen from SEQ ID NO: 2 which comprises ~~, or fragments comprising~~ at least ten contiguous amino acids thereof,
- ~~(f) the polypeptide of (a), (b), (c), (d), or (e) wherein the N-terminal Met residue is deleted; or~~
- ~~(g) the polypeptide of (a), (b), (c), (d), (e), or (f) wherein the secretory amino acid sequence is deleted;~~

wherein said polypeptide elicits antibodies specific for BVH-P7 of *S. pyogenes*.

**Claim 18 (Cancelled)**

**Claim 19 (Currently Amended)** A chimeric polypeptide comprising two or more polypeptides, each having a sequence chosen from SEQ ID NO: 2, and each of at least ten contiguous amino acids thereof; provided that the polypeptides are linked to form a chimeric polypeptide, wherein said chimeric polypeptide elicits antibodies specific for BVH-P7 of *S. pyogenes*.

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**Claim 20 (Previously Presented)** A chimeric polypeptide comprising two or more polypeptides, wherein at least one polypeptide comprises an amino acid sequence of at least ten contiguous amino acids chosen from SEQ ID NO: 2; provided that the polypeptides are linked to form a chimeric polypeptide, wherein said chimeric polypeptide elicits antibodies specific for BVH-P7 of *S. pyogenes*.

**Claim 21 (Previously Presented)** A pharmaceutical composition comprising a polypeptide according to claim 17 and a pharmaceutically acceptable carrier, diluent or adjuvant.

**Claim 22 (Withdrawn)** A method for prophylactic or therapeutic treatment of pharyngitis, erysipelas and impetigo, scarlet fever, and invasive diseases such as bacteremia and necrotizing fasciitis in a host susceptible to pharyngitis, erysipelas and impetigo, scarlet fever, and invasive diseases such as bacteremia and necrotizing fasciitis and also toxic shock comprising administering to said host a prophylactic or therapeutic amount of a composition according to claim 21.

**Claim 23 (Withdrawn)** A method for prophylactic or therapeutic treatment of *Streptococcus pyogenes* bacterial infection in a host susceptible to *Streptococcus pyogenes* infection comprising administering to said host a prophylactic or therapeutic amount of a composition according to claim 21.

**Claim 24 (Withdrawn)** A method according to claim 22 wherein the host is an animal.

**Claim 25 (Withdrawn)** A method according to claim 22 wherein the host is a human.

**Claim 26 (Withdrawn)** A method for diagnostic of streptococcal infection in a host susceptible to streptococcal infection comprising

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- (a) obtaining a biological sample from a host;
- (b) incubating an antibody or fragment thereof reactive with a streptococcal polypeptide of claim 17 with the biological sample to form a mixture; and
- (c) detecting specifically bound antibody or bound fragment in the mixture which indicates the presence of streptococcal.

**Claim 27 (Withdrawn)** A method for detection of antibody specific to streptococcus antigen in a biological sample comprising

- (a) obtaining a biological sample from a host;
- (b) incubating one or more streptococcal polypeptides of claim 17 or fragments thereof with the biological sample to form a mixture; and
- (c) detecting specifically bound antigen or bound fragment in the mixture which indicates the presence of antibody specific to streptococcus.

**Claim 28 (Withdrawn)** A method of preparing a pharmaceutical composition for the prophylactic or therapeutic treatment of streptococcal infection comprising combining a polypeptide according to claim 17 with a pharmaceutically acceptable carrier, diluent or adjuvant.

**Claim 29 (Withdrawn)** A kit for detection or diagnosis of streptococcal infection comprising a polypeptide according to claim 17, and instructions for use of the polypeptide in the detection or diagnosis of streptococcal infection.

**Claim 30 (Currently Amended)** A pharmaceutical composition comprising a chimeric polypeptide according to ~~claim 18~~ claim 19 and a pharmaceutically acceptable carrier, diluent or adjuvant.

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**Claim 31 (Withdrawn)** A method for diagnostic of streptococcal infection in a host susceptible to streptococcal infection comprising

- (d) obtaining a biological sample from a host;
- (e) incubating an antibody or fragment thereof reactive with a streptococcal polypeptide of claim 18 with the biological sample to form a mixture; and
- (f) detecting specifically bound antibody or bound fragment in the mixture which indicates the presence of streptococcal.

**Claim 32 (Withdrawn)** A method for detection of antibody specific to streptococcus antigen in a biological sample comprising

- (a) obtaining a biological sample from a host;
- (b) incubating one or more streptococcal polypeptides of claim 18 or fragments thereof with the biological sample to form a mixture; and
- (c) detecting specifically bound antigen or bound fragment in the mixture which indicates the presence of antibody specific to streptococcus.

**Claim 33 (Withdrawn)** A method of preparing a pharmaceutical composition for the prophylactic or therapeutic treatment of streptococcal infection comprising combining a polypeptide according to claim 18 with a pharmaceutically acceptable carrier, diluent or adjuvant.

**Claim 34 (Withdrawn)** A kit for detection or diagnosis of streptococcal infection comprising a polypeptide according to claim 18, and instructions for use of the polypeptide in the detection or diagnosis of streptococcal infection.

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**Claim 35 (Currently Amended)** An isolated polypeptide of claim 17, which comprises at least one epitope of at least ten contiguous amino acids that elicits antibodies specific for *S. pyogenes*.

**Claim 36 (Cancelled)**

**Claim 37 (Currently Amended)** An isolated polypeptide of claim 17, having at least 95% amino acid identity to ~~a second polypeptide having an~~ the amino acid sequence set forth in ~~comprising~~ SEQ ID NO: 2, or fragments thereof comprising at least ten contiguous amino acids.

**Claim 38 (Previously Presented)** An isolated polypeptide of claim 17 which is SEQ ID NO:2, or fragments thereof comprising at least ten contiguous amino acids.

**Claim 39 (Cancelled)**

**Claim 40 (Currently Amended)** An isolated polypeptide of claim ~~17~~ 19, which is SEQ ID NO:2.

**Claim 41 (Previously Presented)** An isolated BVH-P7 polypeptide from a *S. pyogenes* strain comprising at least 90% amino acid sequence identity to SEQ ID NO:2, or fragments thereof comprising at least ten contiguous amino acids thereof, and wherein said polypeptide comprises at least one epitope that elicits antibodies specific for *S. pyogenes*.

**Claim 42 (Currently Amended)** An isolated polypeptide of claim 17, wherein said polypeptide is encoded by a polynucleotide which hybridizes to the complement of SEQ ID NO:1 under stringent conditions.

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**Claim 43 (Currently Amended)** An isolated polypeptide of claim + 17, comprising a polypeptide which is:

- (a) a polypeptide comprising at least 70% amino acid sequence identity along its entire length to the complete polypeptide of the amino acid sequence set forth in SEQ ID NO:2;
- ~~(b) the polypeptide of (a), wherein the N-terminal Met residue is deleted; or~~
- ~~(c) the polypeptide of (a) or (b), wherein the secretory amino acid sequence is deleted,~~  
wherein said polypeptide is capable of eliciting an immune response specific to BVH-P7 of *S. pyogenes*.

**Claim 44 (Currently Amended)** An isolated polypeptide of ~~claim 1~~, comprising a polypeptide which is:

- (a) a polypeptide comprising at least 90% amino acid sequence identity along its entire length to the complete polypeptide of the amino acid sequence set forth in SEQ ID NO:2; wherein said polypeptide is capable of eliciting an immune response specific to BVH-P7 of *S. pyogenes*
- ~~(b) the polypeptide of (a), wherein the N-terminal Met residue is deleted; or~~
- ~~(c) the polypeptide of (a) or (b), wherein the secretory amino acid sequence is deleted.~~

**Claim 45 (Currently Amended)** An isolated polypeptide of ~~claim 1~~, comprising a polypeptide which is:

- (a) a polypeptide comprising at least 95% amino acid sequence identity along its entire length to the complete polypeptide of the amino acid sequence set forth in SEQ ID NO:2;
- ~~(b) the polypeptide of (a), wherein the N-terminal Met residue is deleted; or~~
- ~~(c) the polypeptide of (a) or (b), wherein the secretory amino acid sequence is deleted,~~

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wherein said polypeptide is capable of eliciting an immune response specific to BVH-P7 of *S. pyogenes*.

**Claim 46 (New)** An isolated polypeptide of Claim 17, wherein said polypeptide lacks an N-terminal Met residue.

**Claim 47 (New)** An isolated polypeptide of Claim 17, wherein said polypeptide lacks a secretory amino acid sequence.

**Claim 48 (New)** An isolated chimeric polypeptide of Claim 19, wherein said polypeptide lacks an N-terminal Met residue or which lacks a secretory amino acid sequence.

**Claim 48 (New)** An isolated chimeric polypeptide of Claim 20, wherein said polypeptide lacks an N-terminal Met residue or which lacks a secretory amino acid sequence.

**Claim 49 (New)** A pharmaceutical composition comprising a polypeptide according to claim 38 and a pharmaceutically acceptable carrier, diluent or adjuvant.

**Claim 50 (New)** A pharmaceutical composition comprising a polypeptide according to claim 45 and a pharmaceutically acceptable carrier, diluent or adjuvant.

**Claim 51 (New)** An isolated polypeptide of Claim 17, comprising a polypeptide which is:  
a polypeptide comprising at least 95% amino acid sequence identity along its entire length to the complete polypeptide of the amino acid sequence set forth in SEQ ID NO:2, or fragments thereof comprising at least ten amino acids, and which is encoded by a polynucleotide



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which hybridizes under stringent conditions to the complement of SEQ ID NO:1, wherein said polypeptide is capable of eliciting an immune response specific to BVH-P7 of *S. pyogenes*.

**Claim 52 (New)** An isolated polypeptide of Claim 17, comprising a polypeptide which is:  
a polypeptide comprising at least 95% amino acid sequence identity along its entire length to the complete polypeptide of the amino acid sequence set forth in SEQ ID NO:2, and which is encoded by a polynucleotide which hybridizes under stringent conditions to the complement of SEQ ID NO:1, wherein said polypeptide is capable of eliciting an immune response specific to BVH-P7 of *S. pyogenes*.